

## DETAILED ACTION

### ***Response to Arguments***

1. Applicant's arguments filed 1/31/08 have been fully considered but they are not persuasive. Applicant references a subsequent publication of the present inventor (JAT-2004) in the arguments. This reference is not prior art, impermissible hindsight reasoning, and new matter.
2. Applicant argues—with MPEP § 2143.01 as allusion—that a *prima facie* case of obviousness cannot be established if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified. It is the examiner's assertion, however, that the Paul reference discloses appropriate motivation to change the mechanism of the Anne reference. Some of oxidizing agents of Anne may react poorly with the chromogenic compounds in the absence of ferrous ions, but this motivation to include ferrous ions is included in the Paul reference as mentioned below (page 462, right column). In other words, the Paul reference discloses motivation to improve the mechanism of Anne.
3. As for the assertion that Applicant reserves the right to filed a Declaration Under 37 C.F.R. § 1.131, it should be noted that no such Declaration has been filed at the time of this office action. Therefore, the Paul reference qualifies as appropriate USC 102(a) and 103(a) matter.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-9, 11, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anne (US 2002/0160439 A1) in view of Paul ("Effects of Oxidizing Adulterants...").

7. Regarding claims 1-4, 6, 11, 16, and 17, Anne discloses a method of detecting oxidants of a urine sample comprising: adding a chromogenic compound to said urine sample and detecting the presence or absence of a chromogenic reaction product (paragraph 9); determining a concentration of said chromogenic reaction product (Table 1); determining if said concentration signifies adulteration of said urine sample (paragraph 30). Anne does not disclose the addition of a source of ferrous ions to a urine sample. The applicant, in a paper jointly written with Aaron Jacobs, discloses a

method of detecting adulteration of a urine sample using a ferrous ammonium sulfate (page 462, right column). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use chromogenic compounds to measure the reduction of the ferrous ions to ferric ions. Paul discloses ferrous ions as an indicator for the presence of oxidants and chromogenic compounds are a well-known method to measure concentrations of both oxidizing and reducing agents. Providing a color effect to test for the oxidants of Paul is obvious. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

8. Regarding claim 5, Anne discloses chromates and nitrites (paragraph 4) and hydrogen peroxide (paragraph 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the other oxidants of claim 4 not explicitly mentioned because they are all known oxidants.

9. Regarding claim 7, Anne discloses the method of claim 6 wherein said chromogenic compound is 2,2'-Azino-bis(3-ethylbenzthiazoline-6-sulfonic acid), and wherein said chromogenic reaction product is a chromogenic oxidation product (paragraph 9).

10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use N,N-Dimethylphenylenediamine, and 2-Amino-p-cresol, as

well, since they perform the same function as 2,2'-Azino-bis(3-ethylbenzthiazoline-6-sulfonic acid).

11. Regarding claims 8, 9, and 18, Anne discloses the concentration reaction product being detected visually and spectrophotometrically (paragraph 30).

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anne (US 2002/0160439 A1) and Paul ("Effects of Oxidizing Adulterants...") as applied to claim 4 above, and further in view of Kightlinger (US 4,558,100).

13. Neither Anne nor Paul discloses the use of ferrous ammonium sulfate with hydrochloric acid in the presence of vanadium. Kightlinger, however, discloses an initiator system for ferrous ions that consists of vanadium (column 2, lines 44-50), ferrous ammonium sulfate (column 2, lines 50-52), and hydrochloric acid (see examples 1 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the known method of Kightlinger to produce ferrous ions for the experiment of Anne and Paul. Kightlinger discloses that vanadium is a suitable promoter for the reaction between ferrous ammonium sulfate and hydrochloric acid.

14. Claims 12-15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anne (US 2002/0160439 A1) and Paul ("Effects of Oxidizing Adulterants...") as applied to claim 11 above, and further in view of Banerjee ("Urinary Hydrogen Peroxide...").

15. Regarding claim 12, Neither Anne nor Paul disclose the use of Xylenol orange, 8-Hydroxy-7-iodo-5-quinoline-sulfonic acid, or 4,5-Dihydroxy-1,3-benzene-di-sulfonic acid as a chromogenic compound to produce a chromogenic complex. Banerjee, however, discloses the use of oxidizing "ferrous ions to ferric ions which then bound with xylenol

orange present in the reagent to form a colored complex" (see page 207, first paragraph). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use xylenol orange—or any analogous compound such as those claimed in claim 12—to detect how much iron is reduced to form a color change. Xylenol orange is a well-known, suitable chromogenic compound for the purpose of Ann and Paul. The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

16. Regarding claims 13 and 14, Anne discloses the concentration reaction product being detected visually and spectrophotometrically (paragraph 30).

17. Regarding claim 15, Paul discloses the source of ferrous ions in excess (see Table 1).

18. Claims 19-21 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anne (US 2002/0160439 A1) in view of Paul ("Effects of Oxidizing Adulterants...").

19. Regarding claims 19 and 20, Anne discloses a method of detecting adulteration of a urine sample comprising: adding a chromogenic compound to said urine sample and detecting the presence or absence of a chromogenic reaction product (paragraph 9); determining a concentration of said chromogenic reaction product (Table 1); determining if said concentration signifies adulteration of said urine sample (paragraph 30). Anne does not disclose the addition of a source of ferrous ions to a urine sample.

The applicant, in a paper jointly written with Aaron Jacobs, discloses a method of

detecting adulteration of a urine sample using a ferrous ammonium sulfate (page 462, right column). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use chromogenic compounds to measure the reduction of the ferrous ions to ferric ions. Paul discloses ferrous ions as an indicator for the presence of oxidants and chromogenic compounds are a well-known method to measure concentrations of both oxidizing and reducing agents. Providing a color effect to test for the oxidants of Paul is obvious. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded and predictable results to one of ordinary skill in the art at the time of the invention.

20. Regarding claim 21, Anne discloses the method of claim 19 wherein said chromogenic compound is 2,2'-Azino-bis(3-ethylbenzthiazoline-6-sulfonic acid), and wherein said chromogenic reaction product is a chromogenic oxidation product (paragraph 9).

21. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use N,N-Dimethylphenylenediamine, and 2-Amino-p-cresol, as well, since they perform the same function as 2,2'-Azino-bis(3-ethylbenzthiazoline-6-sulfonic acid).

22. Regarding claims 23 and 24, Anne discloses the concentration reaction product being detected visually and spectrophotometrically (paragraph 30).

23. Regarding claims 25-27, both Anne and Paul disclose control urine oxidation groups to compare concentrations with (see Table 1 of Anne and Results and Discussion of Paul). The units for measurement were not milliequivalents per liter of oxidants, however. It would have been obvious to one having ordinary skill in the art at the time the invention was made to convert the units of Anne or Paul to those desired as the difference is simply a conversion factor well known to one skilled in the art.

24. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anne (US 2002/0160439 A1) and Paul ("Effects of Oxidizing Adulterants...") as applied to claim 19 above, and further in view of Banerjee ("Urinary Hydrogen Peroxide...").

25. Neither Anne nor Paul disclose the use of Xylenol orange, 8-Hydroxy-7-iodo-5-quinoline-sulfonic acid, or 4,5-Dihydroxy-1,3-benzene-di-sulfonic acid as a chromogenic compound to produce a chromogenic complex. Banerjee, however, discloses the use of oxidizing "ferrous ions to ferric ions which then bound with xylenol orange present in the reagent to form a colored complex" (see page 207, first paragraph). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use xylenol orange—or any analogous compound such as those claimed in claim 22—to detect how much iron is reduced to form a color change. Xylenol orange is a well-known, suitable chromogenic compound for the purpose of Ann and Paul. The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

***Allowable Subject Matter***

26. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

27. The limitation of 29 meq/L of oxidant concentration is not found or suggested in the prior art.

***Conclusion***

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IMRAN AKRAM whose telephone number is (571)270-3241. The examiner can normally be reached on 10-7 Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on 571-272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IA

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